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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/620,246 | 07/15/2003 | Peter Andersen | 670001-2002.1A | 8860 |
| 20999 | 7590 | 04/27/2006 | EXAMINER | |
| FROMMER LAWRENCE & HAUG 745 FIFTH AVENUE- 10TH FL. NEW YORK, NY 10151 | | | SWARTZ, RODNEY P | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1645 | |

DATE MAILED: 04/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|-------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/620,246 | ANDERSEN ET AL. | |
| | Examiner | Art Unit | |
| | Rodney P. Swartz, Ph.D. | 1645 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on ____.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-47 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) Claim(s) 3,4,33,35,37-43 and 45 is/are allowed.
- 6) Claim(s) 1,2,5-32,34,44,46 and 47 is/are rejected.
- 7) Claim(s) 2,5,16,25 and 36 is/are objected to.
- 8) Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 15July2003 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. 09/050,739.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
 Paper No(s)/Mail Date ____.

- 4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date. ____.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: ____.

DETAILED ACTION

1. Claims 1-47 are pending and under consideration.

Information Disclosure Statement

2. USPTO form PTO/SB/05, Utility Patent Application Transmittal, received 15 July 2003, indicates that an Information Disclosure (copy from parent) accompanies the application. However, no IDS has been found in the application papers, and no IDS is listed on the Certificate of Mailing document.

A copy of the listed IDS is required if the references are to be considered.

Specification

3. The disclosure is objected to because of the following informalities:
Throughout the entire specification, references are cited by Name and year, but no listing is provided with the required information.
Page i, line 1, "n" should be "on".
Page 28, lines 31-32, *Bacillus subtilis* and *Salmonella* should be in italics.
Page 29, line 1, *typhimurium* and *Serratia marcesans* should be in italics.
Page 37, line 33, "*Eschericia*" should be "*Escherichia*".
Page 48, line 25 contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.
Page 62, line 18 contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.
Page 63, line 17 contains an embedded hyperlink and/or other form of browser-

executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Page 75, line 17 contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Page 79, line 22 contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

page 87, line 26 contains improper handwritten notation, i.e., 2-DE-PAGE.

Page 88, line 12 contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Appropriate correction is required.

Sequence Identifier Requirement

4. M.P.E.P. §2422.02, third paragraph, recites that "the sequence identifier ("SEQ ID NO:X") must be used, either in the drawing or in the Brief Description of the Drawings." Figure 5 contains sequences without the required sequence identifier in either the figure or its Brief Description. Appropriate correction is required.

M.P.E.P. §2422.03, paragraph 9 recites:

5. 37 CFR 1.821(d) requires the use of the assigned sequence identifier in all instances where the description or claims of a patent application discuss sequences regardless of whether a given sequence is also embedded in the text of the description or claims of an application. This requirement is also intended to permit references, in

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both the description and claims, to sequences set forth in the "Sequence Listing" by the use of assigned sequence identifiers without repeating the sequence in the text of the description or claims. Sequence identifiers can also be used to discuss and/or claim parts or fragments of a properly presented sequence. For example, language such as "residues 14 to 243 of SEQ ID NO:23" is permissible and the fragment need not be separately presented in the "Sequence Listing." Where a sequence is embedded in the text of an application, it must be presented in a manner that complies with the requirements of the sequence rules.

Table 2 contains sequences without the required sequence identifiers.

Table 4 contains sequences without the required sequence identifiers.

Claim Objections

6. Claim 2 is objected to because of the following informalities: in line 2, "SEQ ID NO:88, of" should be "SEQ ID NO:88, or". Appropriate correction is required.

7. Claim 5 is objected to because of the following informalities: in line 4, "isimmunologically" should be "is immunologically". Appropriate correction is required.

8. Claim 16 is objected to because of the following informalities: the first instance of PBMC should be defined. Appropriate correction is required.

9. Claim 25 is objected to because of the following informalities: in line 2, "and pharmaceutically" should be "and a pharmaceutically". Appropriate correction is required.

10. Claim 36 is objected to because of the following informalities: in line 2, "and pharmaceutically" should be "and a pharmaceutically". Appropriate correction is required.

Claim Rejections - 35 USC § 112

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claim 23 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear what are the individual components of the Markush listing of fusion partners because the grouping ends with "and MPB59 and at least one T-cell epitope of MBP59".

13. Claim 34 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear what are the individual components of the Markush listing of fusion partners because the grouping ends with "and MPB59 and at least one T-cell epitope of MBP59".

14. Claim 44 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear what is the definition of "tool". For example, is it a composition or a composition and apparatus?

15. Claims 1, 2, 5-32, 46, and 47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 2, 5, 6, 8, 9, 12, 13, 14, 15, 47 recite that fragments or antigens "derived" from mycobacteria. It is unclear what are the metes and bounds of the term because the specification does not define "derived". It is recommended that the term be replaced with "isolated" or "purified".

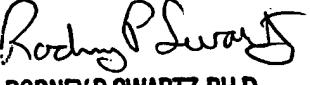
Conclusion

16. Claims 1, 2, 5-32, 34, 44, 46, and 47 are rejected. Claims 2, 5, 16, 25, and 36 are objected to for informalities. Claims 3, 4, 33, 35, 37-43, and 45 appear to be allowable.
17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Thursday from 5:30 AM to 4:00 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F. Smith, can be reached on (571)272-0864.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


RODNEY P SWARTZ, PH.D
PRIMARY EXAMINER
Art Unit 1645

April 25, 2006